Initial Approval: September 14, 2005
Revised Dates: July 8, 2015; July 9, 2014
September 12, 2007; May 10, 2006

**CRITERIA FOR PRIOR AUTHORIZATION**

Somatropin Products

**PROVIDER GROUP** Pharmacy

**MANUAL GUIDELINES** The following drug requires prior authorization:
Somatropin products

## Prior Authorization for Initiation of Growth Hormone in Children

**CRITERIA FOR PEDIATRIC GROWTH HORMONE DEFICIENCY (GHD):** (must meet all of the following)

- Patient must have been evaluated by a Pediatric Endocrinologist or Pediatrician limiting practice to pediatric endocrinology.
- Must have radiological evidence of open epiphyseal growth plates (>16 for boys and >15 for girls).
- Diagnosis must be presented upon request.
- Height velocity must be < 25$^{th}$ percentile for age
    - Requires at least 6 months of growth data
    - Growth curve must be submitted
    - EXCEPTION: neonatal hypopituitarism/hypoglycemia
- Normal thyroid function tests (TSH 0.4-4.0 mIU/L)
- Failure to respond to 2 growth hormone secretagogues with peak < 10ng/mL
    - MRI required for neonatal growth hormone deficiency AND those with peak < 5ng/mL
    - EXCEPTION: neonatal hypopituitarism/hypoglycemia where either GH peak < 10ng/mL during documented hypoglycemia is indication of GH deficiency OR documented structural abnormalities of the pituitary/hypothalamus (ectopic neurohypophysis, septo-optic dysplasia, or other midline defects)
- Request should be for any of the following:
    - Tev-Tropin®, Omnitrope®, Humatrope®, Norditropin®, Nutropin®, Saizen®, Genotropin®, Zomacton®

**CRITERIA FOR PANHYPOPITUITARISM:** (must meet all of the following)

- Patient must have been evaluated by a Pediatric Endocrinologist or Pediatrician limiting practice to pediatric endocrinology.
- Must have radiological evidence of open epiphyseal growth plates (>16 for boys and >15 for girls).
- Diagnosis must be presented upon request.
- Patient must have documented deficiencies of AT LEAST one pituitary hormone; TSH, ACTH, LH/FSH, ADH.
    - Deficiencies in thyroid and Cortisol must be treated before performance of the GH stimulation test.
- Height velocity < 25$^{th}$ percentile for age:
    - Requires at least 6 months of growth data
    - Growth curve must be submitted
    - EXCEPTION: neonatal hypopituitarism/hypoglycemia
- Degree of GH deficiency must be documented by response to 2 GH secretagogues:
    - Patient must be on stable doses of other replacement hormones before performing stimulation tests.
    - Normal thyroid levels documented before testing (TSH 0.4-4.0 mIU/L).
    - < 5ng/mL = severe and < 10ng/mL = deficiency
    - EXCEPTION: – neonatal hypopituitarism/hypoglycemia where either GH peak < 10ng/ml during documented hypoglycemia is indication of GH deficiency or documented structural abnormalities of the pituitary/hypothalamus (ectopic neurohypophysis, septo-optic dysplasia, or other midline defects). Deficiency can be documented by failure to respond to secretagogues but is not required

**CRITERIA FOR CHRONIC RENAL INSUFFICIENCY (CRI):** (must meet all of the following)

- Patient must have been evaluated by a Pediatric Endocrinologist or Pediatrician limiting practice to pediatric endocrinology.
- Must have radiological evidence of open epiphyseal growth plates (>16 for boys and >15 for girls).
- Diagnosis must be presented upon request.
- Patient must have a confirmed diagnosis of CRI by a Pediatric Nephrologist.
- Height velocity < 25$^{th}$ percentile for age:
    - Requires at least 6 months of growth data
    - Growth curve must be submitted
- Request must be for one of the following:
    - Nutropin®

**CRITERIA FOR TURNER OR NOONAN SYNDROME:** (must meet all of the following)

- Patient must have been evaluated by a Pediatric Endocrinologist or Pediatrician limiting practice to pediatric endocrinology.
- Must have radiological evidence of open epiphyseal growth plates (>16 for boys and >15 for girls).
- Diagnosis must be presented upon request.
- Patient must have a confirmed diagnosis of Turner or Noonan syndrome by karyotype.
- Patient must have normal thyroid function tests (TSH 0.4-4.0 mIU/L).
- Height velocity < 25$^{th}$ percentile for age or height < 5$^{th}$ percentile:
    - Requires at least 6 months of growth data
    - Growth curve must be submitted
- Request must be for one of the following:
    - Turner Syndrome
        - Omnitrope®, Humatrope®, Norditropin®, Nutropin®, Genotropin®
    - Noonan Syndrome
        - Norditropin®

**CRITERIA FOR PRADER-WILLI SYNDROME (PWS):** (must meet all of the following)

- Patient must have been evaluated by a Pediatric Endocrinologist or Pediatrician limiting practice to pediatric endocrinology.
- Must have radiological evidence of open epiphyseal growth plates (>16 for boys and >15 for girls).
- Diagnosis must be presented upon request.
- Patient must have a confirmed diagnosis of PWS by a Geneticist.
- Patient must have normal thyroid function tests (TSH 0.4-4.0 mIU/L).
- DEXA scan for body composition
- Absence of obstructive sleep apnea by sleep study or treated obstructive sleep apnea
- Height velocity < 25$^{th}$ percentile for age or height < 5$^{th}$ percentile:
    - Requires at least 6 months of growth data
    - Growth curve must be submitted
- Request must be for one of the following:
    - Omnitrope®, Genotropin®

**Length of Approval:** 6 months

## Prior Authorization for Renewal of Growth Hormone in Children

- Renewal of GH in children:
    - History and physical notes, and growth curve from pediatric endocrinologist dated within 6months of request
    - Documented catch-up growth unless at target height percentile
- B. Rationale for discontinuing GH therapy
    - Growth velocity < 2cm/year while on GH therapy
    - Noncompliance with GH therapy plan
        - Compliance is defined as greater than or equal to 85% adherence to regimen (no more than one missed dose per week on average)
        - Prescriber must attest to patient adherence, and prescription claims data may be used to verify adherence
    - Recommendations of treating pediatric nephrologist or endocrinologist due to changes in underlying conditions
    - Failure to show change in body composition, lipid profile, or growth rate in Prader-Willi Syndrome (PWS)

**Length of Renewal:** 6 months

## Prior Authorization for Growth Hormone in Adults

- Must be prescribed by or in consultation with an endocrinologist
- Patient must have one of the following:
    - diagnosis of pituitary insufficiency confirmed by growth hormone stimulation test (< 5ng/mL serum concentration) and below normal IGF-1/IGFBP3 (see table for normal ranges)
    - diagnosis of panhypopituitarism including those with surgical or radiological eradication of pituitary confirmed by MRI or CT scan
- If non-preferred Growth Hormone medication is being requested, then the Growth Hormone PDL form must also be completed and submitted for processing. Clinical Reviewers will follow established PDL guidelines. (Please note that for non-preferred drug requests the documentation must meet established clinical and PDL criteria to be approved. For requests for preferred drug then only the established clinical criteria must be met.)
- Request must be for one of the following:
    - Omnitrope®, Humatrope®, Norditropin®, Nutropin®, Saizen®, Genotropin®

**Length of Approval:** 12 months

**IGF-1 Normal Ranges by Age**

| Age Range | IGF-1 Normal Range |
|---|---|
| 16-24 | 182-780 ng/mL |
| 25-39 | 114-492 ng/mL |
| 40-54 | 90-360 ng/mL |
| 55+ | 71-290 ng/mL |

**IGFBP3 Normal Ranges by Age**

| Age Range | IGFBP3 Normal Range |
|---|---|
| 18 years | 3.1-7.9 mcg/mL |
| 19 years | 2.9-7.3 mcg/mL |
| 20 years | 2.9-7.2 mcg/mL |
| 21-25 years | 3.4-7.8 mcg/mL |
| 26-30 years | 3.5-7.6 mcg/mL |
| 31-35 years | 3.5-7.0 mcg/mL |
| 36-40 years | 3.4-6.7 mcg/mL |
| 41-45 years | 3.3-6.6 mcg/mL |
| 46-50 years | 3.3-6.7 mcg/mL |
| 51-55 years | 3.4-6.8 mcg/mL |
| 56-60 years | 3.4-6.9 mcg/mL |
| 61-65 years | 3.2-6.6 mcg/mL |
| 66-70 years | 3.0-6.2 mcg/mL |
| 71-75 years | 2.8-5.7 mcg/mL |
| 76-80 years | 2.5-5.1 mcg/mL |
| 81-85 years | 2.2-4.5 mcg/mL |